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SAFETY AND EFFECTIVENESS SUMMARY - STARKEY MA-3

NAME OF DEVICE: Starkey MA-3 air conduction combination hearing aid / tinnitus masker.

TYPE OF DEVICE: Standard BTE air conduction hearing aid -- Substantially equivalent to the Starkey CE-8 TML/TMC hearing aid, (K940667)

INTENDED USE: To assist in compensating for hearing loss by amplifying sound as it comes into the ear and to generate a pleasant white noise stimulus to aid in masking the user's tinnitus (or ringing in the ears)

FEATURES: Adjustable hearing aid volume control, adjustable masker volume controls, control for adjusting the masker frequency.

ASSEMBLY: Assembled from standard components that are widely used in hearing aid devices throughout the industry.

TECHNICAL CHARACTERISTICS: Technical specifications comply with ANSI S3.22-1987

FIT: Frequency response varying based on the needs of the patient. Tolerances are maintained to a ± 4 dB range for SSPL and slope, with ± 5 dB for gain.

CONTROLS: Volume controls, similar to those used on other hearing aid devices. Potentiometers or switches may be incorporated as options require. Any pots or switches are similar to those used in other hearing aid devices.

POWER: Standard 1.4 V type 675 hearing aid battery.

10/3/96

SUMMARY– STARKEY MA-3 SUBSTANTIAL EQUIVALENCE

The Starkey MA-3 air conduction masker aid is designed to be a behind-the-ear hearing aid. This form of hearing aid is intended to be received by a Hearing Health Professional in a completed form, not being intended for final assembly.

The Starkey MA-3 is substantially equivalent to the Starkey CE-8 TML/TMC (K940667). The Starkey MA-3 is a Starkey BTE Hearing Aid with an additional white noise generating circuit which can be tuned to match the frequency and intensity of ringing in the patient's ears (head). The patient has a volume control for this circuit. The hearing aid and masker circuits operate independently of each other, and can be used simultaneously, or either can be used alone. Variable high and low frequency cut potentiometers can be set by a Dispenser to tune to more specific frequencies. All other aspects of this hearing aid are similar to the Starkey CE-8 TML/TMC.

Starkey MA-3

- BTE
- Adjustable Volume Control
- Adjustable Masker Level Control
- Variable Low Frequency Cut (L)
- Variable High Frequency Cut (H)
- Dispenser can tailor to meet individual needs using (L) and (H).
- Made with standard hearing aid parts
- Uses standard hearing aid 675 battery

Starkey CE-8 TML/TMC

- Custom ITE
- Adjustable Volume Control
- Adjustable Masker Frequency
- Adjustable Masker Level Control
- Color Coded for Left and Right
- Hearing aid response tailored to individual needs
- Made with standard hearing aid parts
- Uses standard hearing aid 13 battery